Seres Therapeutics to Initiate New SER-109 Clinical Study

March 16, 2017

– Positive SER-109 Type B FDA meeting –

– Seres and FDA reach agreement on key design elements of a new SER-109 Phase 2 study in patients with multiply recurrent C. difficile infection –

– New trial may qualify as a Pivotal Study with achievement of a persuasive clinical effect and addressing FDA requirements –

– Conference call at 8 a.m. ET today –

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Mar. 16, 2017-- Seres Therapeutics Inc., (NASDAQ:MCRB), a leading microbiome therapeutics platform company, today announced plans to initiate a new SER-109 Phase 2 clinical study (ECOSPOR III) in patients with multiply recurrent *Clostridium difficile* (*C. difficile)* infection. The ECOSPOR III study design was finalized following a positive Type B meeting with the U.S. Food and Drug Administration (FDA). In a separate announcement today, Seres reported fourth quarter and full year 2016 financial results and provided an update on multiple ongoing microbiome clinical programs.

Seres plans to initiate a new SER-109 clinical study in approximately 320 patients with multiply recurrent *C. difficile* infection. Study participants will be randomized 1:1 between SER-109 and placebo. To ensure accurate measurement of *C. difficile* infection, diagnosis of recurrent *C. difficile* infection for both study entry and for endpoint analysis will be confirmed by *C. difficile* cytotoxin assay. Patients in the SER-109 arm will receive a total SER-109 dose, administered over three days, approximately 10-fold higher than the dose used in the prior ECOSPOR study. ECOSPOR III will evaluate patients for 24 weeks and the primary endpoint will compare the *C. difficile* recurrence rate in subjects who receive SER-109 verses placebo at up to eight weeks after dosing. The FDA has agreed that this new trial may qualify as a pivotal study with achievement of a persuasive clinical effect and addressing FDA requirements, including clinical and statistical factors, an adequately sized safety database, and certain CMC parameters.

"We are pleased to have received highly constructive guidance from the FDA regarding further SER-109 clinical development and we plan to initiate a new clinical study as soon as possible," said Roger J. Pomerantz, M.D., President, CEO and Chairman of Seres. "Our prior SER-109 studies provided important new biological and clinical data that have advanced our pioneering microbiome therapeutic efforts. Based on our learnings and dialogue with the FDA, we believe that we are now positioned to initiate a robust clinical study that may provide the basis for SER-109 approval. There is an urgent need for improved treatments for *C. difficile* infection, and we believe SER-109 has great potential to address the underlying cause of the disease and become the first approved microbiome therapeutic in this new field of medicine."

Conference Call Information

Seres' management will host a conference call today, March 16, 2017, at 8:00 a.m. ET. To access the conference call, please dial 844-277-9450 (domestic) or 336-525-7139 (international) and reference the conference ID number 84302413. To join the live webcast and access slides to accompany the conference call, please visit the "Investors and Media" section of the Seres website at www.serestherapeutics.com.

About SER-109

SER-109, an oral capsule, is Seres' lead Ecobiotic ® microbiome therapeutic for the treatment of multiply recurrent *C. difficile* infection. SER-109 is a biologically sourced consortium of bacterial spores designed to catalyze a shift in a dysbiotic gastrointestinal microbiome to a healthier state.

About Seres Therapeutics

Seres Therapeutics, Inc. is a leading microbiome therapeutics platform company developing a novel class of biological drugs that are designed to treat disease by restoring the function of a dysbiotic microbiome, where the natural state of bacterial diversity and function is imbalanced. The Phase 2 study of Seres' program SER-109 has been completed in multiply recurrent *Clostridium difficile* infection. Seres' second clinical candidate, SER-287, is being evaluated in a Phase 1b study in patients with mild-to-moderate ulcerative colitis (UC). Seres is also developing SER-262, the first ever synthetic microbiome therapeutic candidate, in a Phase 1b study in patients with primary CDI. For more information, please visit www.serestherapeutics.com. Follow us on Twitter @SeresTx.

Forward-looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements regarding SER-109 development plans, the timing, design, and results of the ECOSPOR III study , the potential for ECOSPOR III to provide different results than the previous ECOSPOR study, the impact analysis of prior clinical studies may have on clinical outcomes, the potential for ECOSPOR III to qualify as a Pivotal Study, dysbiosis as an underlying cause of *C. difficile* and other diseases.

These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: we have incurred significant losses, are not currently profitable and may never become profitable; our need for additional

funding, which may not be available; our limited operating history; the unpredictable nature of our early stage development efforts for marketable drugs; the unproven approach to therapeutic intervention of our microbiome therapeutics; the lengthy and expensive process of clinical drug development, which has an uncertain outcome; potential delays in enrollment of patients which could affect the receipt of necessary regulatory approvals; potential delays in regulatory approval, which would impact the ability to commercialize our product candidates and affect our ability to generate revenue; any fast track or Breakthrough Therapy designation may not lead to faster development, regulatory approval or marketing approval; our possible inability to receive orphan drug designation should we choose to seek it; our reliance on third parties to conduct our clinical trials and the potential for those third parties to not perform satisfactorily; our reliance on third parties to manufacture our product candidates, which may delay, prevent or impair our development and commercialization efforts; our lack of experience in manufacturing our product candidates; the potential failure of our product candidates to be accepted on the market by the medical community; our lack of experience selling, marketing and distributing products and our lack of internal capability to do so; failure to compete successfully against other drug companies; potential competition from biosimilars; failure to obtain marketing approval internationally; post-marketing restrictions or withdrawal from the market; anti-kickback, fraud, abuse, and other healthcare laws and regulations exposing us to potential criminal sanctions; recently enacted or future legislation; compliance with environmental, health, and safety laws and regulations; protection of our proprietary technology; protection of the confidentiality of our trade secrets; changes in United States patent law; potential lawsuits for infringement of third-party intellectual property; our patents being found invalid or unenforceable; compliance with patent regulations; claims challenging the inventorship or ownership of our patents and other intellectual property; claims asserting that we or our employees misappropriated a third-party's intellectual property or otherwise claiming ownership of what we regard as our intellectual property; adequate protection of our trademarks; ability to attract and retain key executives; managing our growth could result in difficulties; risks associated with international operations; potential system failures; the price of our common stock may fluctuate substantially; our executive officers, directors, and principal stockholders have the ability to control all matters submitted to the stockholders; a significant portion of our total outstanding shares are eligible to be sold into the market; unfavorable or lacking analyst research or reports; and we are currently subject to securities class action litigation. These and other important factors discussed under the caption "Risk Factors" in our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission, or SEC, on November 10, 2016 and our other reports filed with the SEC, could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

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